



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,903	08/22/2003	Daniel M. Lieberman	3998P2652	1335
23504	7590	07/11/2006	EXAMINER	
WEISS & MOY PC 4204 NORTH BROWN AVENUE SCOTTSDALE, AZ 85251			CORRIGAN, JAIME W	
			ART UNIT	PAPER NUMBER

3767

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/646,903	Applicant(s) LIEBERMAN, DANIEL M.	
	Examiner Jaime W. Corrigan	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-15, 18-22 and 26-33 is/are rejected.
- 7) ☒ Claim(s) 17, 23-25 and 1116 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

Claim 28 is objected to because of the following informalities: In line 3, "combination" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-7, 9-10, 12-15, 18-19, 28, 30-31, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Lawrence et al. (PN 6,394,996).

Regarding claims 1, 14, 28 Lawrence et al. discloses a method for treating subdural hematomas (See Figures 2, 7; Abstract; Column 2 Lines 61-67, Column 3 Line 1) comprising, in combination, the steps of: inserting (See Column 2 Lines 3-35) a dual lumen catheter (See Figure 2, (38), (40)) into a subdural space; draining (See Figure 2, (38); Abstract, Column 2 Lines 61-67, Column 3 Lines 38-67, Column 1-9) said subdural space of a subdural fluid collection with said dual lumen catheter; and irrigating (See Figure 2, (38); Abstract, Column 2 Lines 61-67, Column 3 Lines 38-67, Column 1-9) said subdural space using said dual lumen catheter.

Regarding claims 2, 30 Lawrence et al. discloses said drainage channel defines drainage perforations (See Figure 2 (66), Column 4 Lines 10-23) proximate said distal portion of said drainage channel and said irrigation channel defines irrigation perforations (See Figure 2 (64), Column 4 Lines 10-23) proximate said distal portion of said drainage channel.

Regarding claims 4, 18, 31 Lawrence et al. discloses a pressure valve (See Column 3 Lines 33-37) coupled to said proximal portion of said irrigation channel (See Figure 2, (38)) said pressure valve dimensioned to regulate (See Figure 1 (32)) a flow of fluid irrigation.

Regarding claim 5 Lawrence et al. discloses an irrigation container (See Figure 1 (10)) dimensioned to retain an irrigation solution, said container being coupled (See Column 3 Lines 1-5) to said pressure valve (See Figure 1 (32)).

Regarding claims 6, 20 discloses a leur (See Column 3 Lines 54-57) lock fitting connecting said container to said pressure valve (See Figure 2 (22)).

Regarding claim 7 discloses a drainage container (See Figure 2 (42)) coupled to a proximal end of said proximal portion of said drainage channel (See Figure 2 (40)), said drainage container dimensioned to receive (See Column 4 Lines 3-9, 45-62) subdural fluid collection from said drainage channel.

Regarding claim 9 Lawrence et al. discloses said distal portion of said drainage channel being coupled (See Figure 2 (38), (40)) lengthwise to said distal portion of said fluid irrigation channel.

Regarding claim 10 Lawrence et al. discloses said distal portion of said drainage channel and said distal portion of said fluid irrigation channel have a length of between approximately 5 and 10 centimeters (See Column 2 Lines 3-6).

Regarding claim 12 Lawrence et al. discloses said dual lumen catheter having a diameter of between approximately 1 and 4 millimeters (See Column 5 Lines 29-32).

Regarding claim 13 Lawrence et al. discloses said dual lumen catheter having a diameter of approximately 2 millimeters (See Column 5 Lines 29-32).

Regarding claim 15 Lawrence et al. discloses providing a drainage (See Figure 2 (38)) channel having a proximal portion and a distal portion; providing an irrigation channel (See Figure 2 (40)) having a proximal portion and a distal portion; wherein said drainage channel and said irrigation channel comprise said dual lumen catheter (See Figure 2, (38), (40)); draining (See Figure 2, (38); Abstract, Column 2 Lines 61-67, Column 3 Lines 38-67, Column 1-9) said subdural space of a subdural fluid collection using said drainage channel of said dual lumen catheter; and irrigating (See Figure 2,

(38); Abstract, Column 2 Lines 61-67, Column 3 Lines 38-67, Column 1-9) said subdural space using said irrigation channel of said dual lumen catheter.

Regarding claim 19 Lawrence et al. discloses providing an irrigation container (See Figure 1 (10)) dimensioned to retain an irrigation solution; coupling said container to said pressure valve; and operating said pressure valve (See Figure 1 (32)) in order to regulate (See Column 3 Lines 33-37) a flow of fluid irrigation from said pressure valve to said irrigation channel.

Regarding claim 33 Lawrence et al. discloses a means (See Figure 1) for inserting the dual lumen catheter into a subdural space.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawrence et al. (PN 6,394,996).

Lawrence et al. discloses drainage perforations with a diameter ranging between .15 to .17 inches (See Column 4 Lines 20-23) and a dual lumen catheter about 4-16 (See Column 2 Lines 3-6) inches long.

Lawrence et al. does not disclose expressly said drainage perforations having a diameter of between approximately .5 and 2 millimeters or dual lumen catheter having a length of between approximately 10 and 30 centimeters.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to increase the drainage perforation size and decrease the catheter length because Applicant has not disclosed that the claimed perforation and catheter sizes provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the perforation and catheter sizes disclosed in Lawrence et al. since both devices are being used to treat the same fluid and debris of a wound site.

Therefore, it would have been an obvious matter of design choice to modify Lawrence et al. to obtain the invention as specified in claims 3, 8.

Claims 6-7, 20-21, 26-27, 29, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawrence et al. (PN 6,394,996) in view of Palestrant (PN 5,002,528).

Lawrence et al. discloses the invention as recited in claims 1, 14 and 28 above, however, fails to disclose a leur lock fitting; a drainage container; a drainage container collecting subdural fluid; draining over three days; irrigating over one to two days; irrigation and drainage locks.

Palestrant teaches that it is conventional in the art to utilize a leur (See Column 3 Lines 54-57) lock fitting connecting said container to said pressure valve (See Figure 2

(22)); a drainage container (See Figure 2 (42)) dimensioned to receive subdural collection fluid from said drainage channel (See Figure 2 (40)); coupling said drainage container (See Figure 2 (42)) to a proximal end of said proximal portion of said drainage channel; and draining said subdural space of said subdural collection fluid so that said drainage container fills with said subdural collection fluid from said subdural space (See Column 4 Lines 3-62); said draining of said subdural space occurring over approximately three days (See Column 2 Lines 9-11); said irrigating of said subdural space occurring over approximately between 1-2 days (See Column 2 Lines 9-11); the dual lumen catheter further comprises: a first (See Figure 2 (20)) lock means for connecting an irrigation container for irrigating a subdural hematoma; and a second (See Figure 2 (32)) lock means for connecting a drainage container for draining said subdural hematoma.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the leur lock fitting and drainage container taught by Palestrant in the Lawrence et al. device since they would improve hematoma irrigation and drainage control.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lawrence et al. (PN 6,394,996) in view of Boss et al. (PN 5,411,883).

Lawrence et al. discloses the invention as recited in claim 14 above, however, fails to disclose the step of drilling a hole into a skull.

Boss et al. teaches that it is conventional in the art to utilize the step of drilling a hole into a skull (See Column 15 Lines 24-30).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized drilling a hole into a skull taught by Boss et al. in the Lawrence et al. device since it would improve catheter effectiveness for draining and irrigating a hematoma.

Allowable Subject Matter

Claims 11, 16-17, 23-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Greenfeld et al. (PN 5,271,735) and Fenton, Jr. et al. (PN 5,190,520) disclose similar subdural drainage devices.

Any inquiry concerning this communication from the Examiner should be directed to Examiner Jaime Corrigan whose telephone number is (571) 272-4858. The Examiner can normally be reached on Monday – Friday from 8:30 a.m. – 6:00 p.m. 2nd Friday off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Kevin C. Sirmons, can be reached on (571) 272-4965. The fax number for this group is (571) 273-8300.

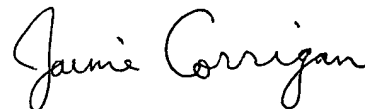
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-3700.

JC

June 27, 2006

Jaime Corrigan



Patent Examiner
Art Unit 3767

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

